

Remarks

Included herewith is a petition for one-month extension of time and authorization to charge the fee to an appropriate deposit account. The time for response is now set to expire on January 26, 2004.

Included herewith is a petition to accept an unintentionally delayed claim for priority. The specification accordingly has been amended to make proper reference to the corresponding PCT application.

Claims 16-18 stand rejected under 35 U.S.C. §102(b) as being anticipated by Field et al. (*Antimicrobial Agents and Chemotherapy*, Vol. 39, pp. 11114-11119 (1995) or *Antiviral Chemistry & Chemotherapy*, Vol. 6, pp. 210-216 (1995).

Claims 16-18 are now limited, via the present amendment, to a method in a human. Both Field et al. references teach only a mouse model, therefore, neither Field et al. reference teaches Applicants' method limited to humans.

Claims 7-15 and 19-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the combined teachings of Harrell et al., *Drug Metabolism and Disposition - the biological fate of chemicals*, Vol. 21, pp.18-23 (1993), abstract only cited; and Field et al. (1995), *supra*.

Field et al. describes the administration of cyclosporine A (CyA) to cause immunosuppression in mice so that they can act as research models. Field et al. does not disclose the use of a combination CyA and penciclovir / famciclovir (FCV) as a therapy to treat HSV infections in mice. Indeed, Field et al. clearly does not contemplate that such a combination could be used for therapy since in order to achieve the objectives of Field et al. the administration of CyA must begin prior to either infection with HSV or administration of antiviral therapy.

Harrell et al. suggest co-administration of CyA and FCV to combat viral infections induced by immunosuppression in organ transplant and bone marrow transplant patients.

However, there is nothing in Harrell et al. or Field et al. to suggest that the co-administration of an antiviral nucleoside analogue and an immunosuppressant may have a greater effect in the treatment of HSV infections when compared to the antiviral nucleoside analogue alone.

Included herewith is the ICAAC Abstract for 1999, submitted in the parent application, showing in the management of recurrent herpes simplex labialis, that a combination of FCV and the topical corticosteroid fluocinonide, significantly reduced maximum lesion size, aborted more lesions and resulted in faster healing time when compared to FCV alone.

Assuming, *arguendo*, that it may have been prima facie obvious to co-administer CyA and FCV to certain patients from the cited references, neither reference teaches or suggests the surprising and unexpected results as reported in the above-cited ICAAC Abstract.

It is submitted that Applicants' specification and claims are in proper form. Applicants respectfully request that the rejection under 35 U.S.C. §102(b) and 103(a) be withdrawn and the pending Claims 7-22 be passed to allowance.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080


Thomas R. Savitsky
Attorney for Applicant
Reg. No. 31,661
(862) 778-7909

Date: January 26, 2004